

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE	:	MASTER DOCKET NO.:
PAULSBORO DERAILMENT CASES	:	1:13-CV-784 (RBK/KMW)
	:	
	:	
ALICE BREEMAN, <i>et al.</i>	:	
	:	
Plaintiffs,	:	CIV NO. 1:12-07468 (RBK/KMW)
	:	
v.	:	
	:	
CONSOLIDATED RAIL	:	
CORPORATION, <i>et al.</i> ,	:	
	:	
Defendants.	:	

**PLAINTIFFS' BRIEF IN OPPOSITION TO DEFENDANTS'
MOTION TO EXCLUDE THE EXPERT REPORT AND
TESTIMONY OF OMOWUNMI OSINUBI, M.D. [ECF #728]**

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INTRODUCTION

On November 30, 2012, a train derailed while crossing the Paulsboro Bridge as a result of the tortious conduct of Defendants Consolidated Rail Corporation, Norfolk Southern Railway Company, and CSX Transportation, Inc. (collectively, “Defendants”). One of the tank cars breached, releasing well over 20,000 gallons of vinyl chloride gas into the air. The gas spread throughout the town.

Plaintiffs Alice Breeman (“Alice” or “Ms. Breeman”) and Savannah Breeman-Rodgers (collectively, “Plaintiffs”) were among the many who were exposed, and they suffered immediate negative health effects. *See, e.g.*, Defs. Mot., Ex. C. (Dec. 11, 2014 Report of Dr. Osinubi (“December 2014 Osinubi Report”)), Plaintiffs retained Omowunmi Osinubi, M.D. as a causation expert in their suit against Defendants, and for purposes of recommending whether medical monitoring would be appropriate.

Defendants have moved to exclude all testimony of Dr. Osinubi based on a litany of purported defects in her methodology, all of which go to weight rather than admissibility. Because Dr. Osinubi’s testimony satisfies the standards of *Daubert* and Fed. R. Evid. 702, Defendants’ motion to exclude must be denied.

BACKGROUND

I. The Derailment Resulted in a Massive Exposure to Vinyl Chloride.

Raelynn Stevenson was drinking her morning cup of coffee at her home

when she witnessed the derailment. She described a vapor cloud that appeared right after the train cars derailed that looked like “the dust that came up the street that you saw on TV on 9/11. That’s what it looked like coming up to my house.”

See Declaration of David Cedar (“Cedar Dec.”) Exhibit A (NTSB Interview of Raelynn Stevenson), at p. 9:15-6; 10:6-16. Before the accident, the weather “was crystal clear. It was a beautiful morning.” *Id.* at 11:17.

Conrail’s engineer confirmed that “as soon as the top of the bridge went down it was almost instantaneously that the fog bank came up out of the Mantua Creek.” *See* Cedar Dec. Exhibit D (Deposition Transcript of Mark Mather (“Mather Dep.”)), p. 103:12-14. Conrail’s engineer described the size of the vapor cloud: “Pretty much the whole neighborhood . . . had a fog.” *Id.* at 113:19-21.

The official Paulsboro police report stated: “as [Patrolman Rodney Richards] was speaking with [Conrail’s] conductor, [he] noticed a smoky fog start to swarm the immediate area and become very thick. The smoky substance that quickly surrounded [him] caused a reaction that made [him] cough several times.” Cedar Dec. Exhibit F (Paulsboro Police Report), p. 2. The recorded communications of the first responders further supports the immediate presence of toxic fog:

7:01 “It’s [the train] is spewing out all kinds of gas.” (Gloucester County 911 call)

7:05 “Rail cars or tank cars have been pierced and have leaked out all of their contents into the creek. The creek is full of vapors from these cars.” (Channel 3 fire Ops.)

7:06 “It’s a major emergency, bridge collapsed and major hazards,

potentially life-threatening...I have an odor out here that they are not familiar with. This odor is hazardous. Hazard released." (Zone 3 Police Radio Channel)

See Exhibit G (Timeline of Events and Communications on November 30, 2012).

The ruptured tank car contained about 25,000 gallons (~ 177,000 pounds) of vinyl chloride. The National Oceanic and Atmospheric Administration (NOAA) ran an Area Locations of Hazardous Atmospheres ("ALOHA") model of what the exposures would be if the entire amount were released through a hole 12 inches in diameter over a time period of two minutes. This model showed that the "toxic threat zone" would extend out two miles from the release area. *See Cedar Dec. Exhibit J.* The toxic threat zones are assessed in terms of Acute Exposure Guideline Levels ("AEGLs") established by the National Advisory Committee managed by the EPA.

Severity Tier	Vinyl Chloride Air Concentration (ppm)			Definition
	Exposure for 10 minutes	Exposure for 30 minutes	Exposure for 60 minutes	
AEGL-1	450	310	250	The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals...
AEGL-2	2,800	1,600	1,200	...could experience notable discomfort, irritation, or certain asymptomatic nonsensory effects. However, the effects are not disabling and are transient and reversible upon cessation of exposure.
AEGL-3	12,000	6,800	4,800	...could experience irreversible or other serious, long-lasting adverse health effects or an impaired ability to escape.

See Exhibit I (NJ DOH Air Quality Consultation).

The highest threat zone, corresponding to AEGL-3 at 4,800 ppm, would extend 1,383 yards, or about 0.8 mile, from the spill site; the next highest threat zone, corresponding to AEGL-2 at 1,200 ppm, would extend from 0.8 to 1.2 miles away from the spill site; and the last threat zone, corresponding to AEGL-1 at 250 ppm, would extend from 1.2 to 2.0 miles away from the spill site. *See* Cedar Dec. Exhibit P . An Interagency Modeling and Atmospheric Assessment Center (“IMAAC”) model similarly estimated that the AEGL-3 zone would be about 0.5 mile in diameter and the total toxic threat zone about 1.0 mile in diameter. *See* Cedar Dec. Exhibit K (IMAAC Model).

Conrail’s contractor determined that when turned to gas, the entire 80,000 kg of vinyl chloride would spread over a surface area of 30,000 square meters and one meter thick. *See* Cedar Dec., Exhibit L (ARCADIS US’s Vinyl Chloride Model). This means that an area encompassing approximately three square blocks of Paulsboro would be 100% vinyl chloride, or, in the alternative, that there would be enough vinyl chloride to contaminate an area of 300 city blocks to a level of 10,000 parts per million if equally disbursed.

II. Paulsboro Refinery Vinyl Chloride Testing Results

Paulsboro Refinery personnel arrived at the scene of the derailment at about 8:30 a.m. with Photo Ionization Detectors (“PID”). They found that the levels of

vinyl chloride in the air were so high that they were unable to “zero” out their equipment. Without being able to “zero” out the PIDs first, the readings on these devices yielded results of 631, 694 and 760 ppm. As analytic chemical expert, Dr. Brian Buckley, explains, these readings need to be multiplied by 1.9 to obtain a vinyl chloride equivalent. See Cedar Dec. Exhibit M (Report of Brian Buckley (“Buckley Report”)), p. 1.

About ten minutes later, the Paulsboro Refinery employees walked a few blocks away to Delaware Street and Billings Avenue to try to zero out their instruments, but instead obtained readings well in excess of 100 ppm. *Id.* at 2. The same meters later on had negative readings ranging from -40 to -60 ppm which is, of course, impossible. *Id.* Dr. Brian Buckley reviewed the Paulsboro Refinery data and opined that the actual vinyl chloride levels present in the air at the time the Paulsboro Refinery readings were taken were “greatly in excess of the readings recorded by the device.” *Id.* at 3. Due to being unable to properly zero the device out and to the excessive saturation of the chemical, the readings from the Paulsboro Refinery PIDs could reasonably be expected to result in much lower numbers than was actually present. *Id.*

III. New Jersey Department of Health Consultations

The New Jersey Department of Health (“DOH”) performed a “Health Consultation” on air quality in Paulsboro following the derailment. The DOH

analyzed the air modeling data that was done and concluded that “[b]ased on modeled estimates and monitoring, peak air concentrations . . . exceeded the EPA’s Acute Exposure Guidance Levels (AEGL) for one hour exposure that are associated with reversible health effects (AEGL-1: 250 ppm) and possibly disabling effects (AEGL-2: 1,200 ppm) or life threatening effects (AEGL-3: 4,800 ppm).” Cedar Dec. Ex. X at 11.

V. Odor Detection and Threshold

Many in Paulsboro complained of the sickly sweet odor of vinyl chloride on the day of the chemical spill. One of the complainants, Stephanie Esposito, a Fox 29 news reporter, tweeted at 9:13 a.m. on November 30th that she “just took a walk down to the roadblock and definitely smell[ed] something sweet.” She described the odor as “a pungent smell [that] hits you like a brick wall when you walk into it”. She was able to smell this odor even though she had a cold. *See* Cedar Dec. Exhibit R, Screenshot of Stephanie Esposito’s Twitter Feed. Ptl. Richards, who had worked in Paulsboro since 2006, testified that the odor of chemical was distinct from the typical smells in the town. He too described it as a “pungent smell”. *See* Cedar Dec. Exhibit S (Deposition Transcript of Rodney Richards (“Richards Dep.”)), p. 31-32.

Dr. Maria Kent, Alice Breeman’s family doctor, testified that multiple patients were concerned about their vinyl chloride exposure and reported

complaints of nausea, headaches, wheezing, confusion, dizziness and dry throat.

See Cedar Dec. Exhibit T (Deposition Transcript of Dr. Maria Kent (“Kent Dep.”)) pp. 41-43. A number of these patients also complained of smelling some kind of chemical odor that day. *Id.*

The Agency for Toxic Substances and Disease Registry (“ATSDR”) also reports the odor threshold for vinyl chloride to be “about 3,000 ppm” noting that it varies significantly among individuals. *See* Cedar Dec. Exhibit V.¹ An odor threshold test performed by Union Carbide on a panel of experts with an average of ten years experience in odor detection and evaluation found that the odor threshold for vinyl chloride was commonly 2,000 ppm, although two of the most sensitive panelists could detect a faint odor at 1,200 ppm. See Cedar Dec. Exhibit W (Union Carbide Corporation Vinyl Chloride Odor Threshold Test).

The New Jersey Department of Health took two surveys of residents of Paulsboro following the train wreck. The first was an in person “door to door” survey and the second was a mailed survey. 50% of the adults in the in-person survey reported smelling or tasting unusual odors; in the mailed survey 69% of households reported that at least one member of the household smelled or tasted an unusual odor. *See* Exhibit X (NJ DOH Health Consultation), p. 8. Among those who reported smelling or tasting an odor in both the in-person and mailed surveys,

¹ The DOH’s hazmat Fact Sheet states “Odor threshold = > 3,000 ppm.”

there were higher frequencies of reported new or worsening symptoms. Also in both surveys, the most frequently reported symptoms among those who smelled an odor were headache, coughing, irritation of the nose and throat, dizziness, irritation or pain or burning of eyes, and difficulty breathing. *Id.* The DOH concluded that:

The symptoms commonly reported are consistent with what is known to occur from exposure to vinyl chloride, specifically headache, irritation of the eyes, nose, throat and lungs, coughing, nausea, and dizziness or lightheadedness. ... [T]here was a similar pattern of reported symptom frequencies between the in person and mailed surveys, as well as with the findings of surveys of emergency responders.

Id. at 12.

The report also found that “symptoms were most commonly reported from evacuated areas and areas within one block of evacuated areas and were least frequent in areas farther than 3,500 feet from the derailment location.” *Id.*

VI. Vinyl Chloride Health Information

The New Jersey DOH hazmat fact sheet for vinyl chloride states:

Vinyl chloride is a CARCINOGEN in humans. There may be no safe level of exposure to a carcinogen.

The acute health effects include the following:

- Exposure to **Vinyl Chloride** can severely irritate and burn the skin and eyes with possible eye damage. Contact with the *liquid or gas* can cause frostbite.
- Inhaling **Vinyl Chloride** can irritate the nose, throat and lungs causing coughing, wheezing and/or shortness of breath.

- **Vinyl Chloride** can cause headache, nausea, vomiting, dizziness, fatigues, weakness and confusion. Higher levels can cause lightheadedness and passing out.

See Cedar Dec. Exhibit Y. OSHA's permissible exposure limit for vinyl chloride is 1 ppm averaged over an 8 hour day. The short-term exposure limit is 5 ppm, not to be exceeded during any 15-minute period. *Id.* OSHA recommends medical monitoring consisting of liver function tests, chest X-rays and lung function tests for workers exposed to 0.5 ppm of vinyl chloride. *See* Cedar Dec. Exhibit Z.

The International Agency for Research on Cancer's (IARC) Monograph on the Evaluation of Carcinogenic Risk to Humans found sufficient evidence that vinyl chloride causes angiosarcomas of the liver and hepatocellular carcinomas (HCC). *See* Cedar Dec. Exhibit AA, p. 425. The same report cited numerous studies which "found evidence of a significant association between exposure to vinyl chloride monomer (VCM) and mortality from liver cirrhosis. *Id.* at 327 (citing The European Multicentric Study); *id.* at 328 (citing Pirastu, et al., 2003). Mastrangelo in 2004 also reported "an association between exposure of VCM and both liver cirrhosis and [hepatocellular carcinoma]." *Id.* at 329; *see also id.* at 349 (cross-sectional study of Hepatocellular Carcinoma in Italy finding association between VCM exposure and both liver cirrhosis/ HCC in vinyl chloride workers). IARC concluded "together with the observation that vinyl chloride increases the risk for liver cirrhosis, which is a known risk factor for hepatocellular carcinoma,

these findings provide convincing evidence that vinyl chloride causes hepatocellular carcinoma as well as angiosarcoma of the liver.” *Id.* at 422.

In addition, the Material Safety Data Sheet of Oxyvinyl issued for this very shipment of vinyl chloride risks among potential health effects states the following:

Inhalation: May cause respiratory tract irritation. Several minutes of exposure to high, but attainable concentrations (over 1,000 ppm) may cause difficulty breathing, central nervous system depression and symptoms such as: ataxia or dizziness, drowsiness or fatigue, loss of consciousness, headache, euphoria and irritability, visual or hearing disturbances, nausea, memory loss. Prolonged high concentration exposure may cause unconsciousness or death. Cardia: Acute intoxication may cause irregular heartbeats.

See Cedar Dec. Exhibit AB, MSDS on Vinyl Chloride (Monomer), p. 10.

Mastrangelo’s 2004 study explicitly concluded that “VCM exposure appears to be an independent risk factor for [hepatocellular carcinoma] and [liver cirrhosis].”

See Cedar Dec. Exhibit AC, Mastrangelo, et al., Increased Risk of Hepatocellular Carcinoma and Liver Cirrhosis in Vinyl Chloride Workers: Synergistic Effect of Occupational Exposure with Alcohol Intake, Vol. 112 (2004), p. 1192.

VII. Statement of Facts Specific to Alice Breeman

As detailed in the December 2014 Osinubi Report (*see* Cuker Dec. Ex. I), on the morning of November 30, 2012, Alice Breeman was preparing to take her children to school and day care. She lives at 120 Jessup Street, which is about a half mile from the site of the derailment. When she left her home that morning she noticed that there was fog and drove through the fog to take her children to school.

Upon hearing that the elementary school was on lockdown she turned around, drove through the fog again, to Tracey's Day Care at 337 Mantua Avenue, about 0.3 miles from the derailment site. She took her children out of the car, walked through the chemical fog to the day care center and was told that they were on lockdown and could not accept any more children. She once again took her children through the fog, back into the car, went to her children's stepmother's house two blocks away from the day care center. She again walked through the fog to drop her children off at their stepmother's house.

Alice proceeded to drive to work through the fog, but had to pull over because of headache and dizziness. She gave up trying to go work and went back, again driving through the fog, to pick up her children at their step mother's house and drive to Williamstown to drop them off at her mother's. Over the next day Alice felt dizzy, short of breath, coughing, wheezing, tired and had two nose bleeds and a headache. She called out of work for three days, November 30, December 3 and 4, 2012, and also complained of smelling a persistent chemical odor.

Alice was seen in the emergency room at Underwood Hospital on December 1, 2012, where she was discharged with a diagnosis of vinyl chloride exposure, epistaxis, reactive airway disease with bronchospasm, and a smoker with a history of diabetes.² Her throat pain rated 5/10, and she had a slight expiratory wheeze.³

² Defendants completely ignore this ER visit when they falsely suggest at p. 15 of

Alice was seen again at Kennedy Hospital on December 3, 2012, with complaints of dizziness, tight chest and shallow breathing.⁴ She was treated with a Ventolin nebulizer and discharged. *See* Defs. Mot. at Ex. D (Dr. Osinubi Addendum Report for Alice Breeman, March 3, 2015 (“Osinubi Addendum Report”)) *See also* Cuker Dec. Ex. J.

Alice was not getting any better and went to see her family doctor, Maria Kent, M.D., complaining of wheezing, nausea, headache, as well as a skin rash. A week before seeing Alice, Dr. Kent was visited by Dr. Michael Holland of CTEH, Conrail’s toxicology consultant. *See* Cuker Dec. Ex. J, Dr. Osinubi Addendum at 2. Dr. Kent sought out advice from Conrail because she had multiple patients coming to her with complaints of nausea, headaches, wheezing, confusion and dizziness, all of which were similar to the symptoms reported by Ms. Breeman. *See id.* Dr. Holland told Dr. Kent that the highest level of vinyl chloride exposure any residents of Paulsboro had been exposed to was 10 parts per million, that no one could have actually smelled vinyl chloride because the odor threshold is 3,000 parts per million, and that any symptoms of vinyl chloride exposure should dissipate after people were removed from exposure. *See* Cuker Dec. Ex. N, Kent

their brief that she was not seen “until three days after the derailment.

³Contrary to Defendants contention at p. 16 of their brief, the Underwood record also documents a complaint of “nausea”. Cuker Dec. Ex. K

⁴Contrary to Defendants contention at p. 16 of their brief, this record shows that she smokes “at .5” which is consistent with smoking half a pack a day. Cuker Dec. Ex. L.

Dep. at 47-50. Thus, when Dr. Kent saw Alice Breeman on December 12, the influence of Dr. Holland caused her to attribute Alice's symptoms to "viral bronchitis or sinusitis" rather than reaction to vinyl chloride. Dr. Kent testified further that the New Jersey Department of Health (NJDOH) survey sharply contradicted what Dr. Holland had told her, and that he also told her that "they would not expect long-term or chronic health effects from the vinyl chloride exposures that happened here." *See* Cuker Dec. Ex. N, Kent Dep. at 43:12-16.

Alice continued to have complaints of coughing, wheezing, shortness of breath and sore throat. *See* Cuker Dec. Ex. I, December 2014 Osinubi Report at 4-5. Dr. Osinubi conducted a two- hour telephone interview of Ms. Breeman on November 21, 2014, and a physical exam on December 6, 2014. On physical exam, Alice demonstrated very frequent episodes of cough spasms, triggered by deep breathing. The chronic cough in turn triggered severe abdominal spasm, which was evident during Dr. Osinubi's clinical assessment. The abdominal exam showed a positive Carnett's sign, indicating the chronic cough had become so severe that the increased abdominal pressure during coughing had caused abdominal cutaneous nerve entrapment syndrome (ACNES). *See id.* at 24. The exam also revealed high pitched wheezing from the throat area. Dr. Osinubi diagnosed a moderately severe chronic cough interfering with sleep. The differential diagnoses were vocal cord dysfunction, reactive airways dysfunction

syndrome (RADS) and interstitial lung disease. *See id.* at 24-26.

Dr. Osinubi concluded that based on the toxic zone exposure modeling done by NOAA and air monitoring assessment compiled by the NJDOH, Ms. Breeman was likely exposed to levels of vinyl chloride greater than 4,800ppm (AEGL-3) since she twice got out of her car within 0.3 miles of the derailment. *See id.* at 17. Dr. Osinubi concluded that although Ms. Breeman had a history of childhood asthma and smoking which “increased her vulnerability and susceptibility to chronic upper and lower airway respiratory disease from vinyl chloride exposure,” *id.* at 27, Dr. Osinubi further noted that “the fact that Ms. Breeman experienced severe headaches and dizziness at the time of peak exposures to vinyl chloride and that her children were somnolent at the time of her exposure, highly suggests that Ms. Breeman (and her children’s) vinyl chloride exposures over that period of time likely exceeded 4,800ppm.” *Id.* at 17. Indeed, symptoms that Ms. Breeman and her children experienced “have been described at exposure levels in the range of 12,000 – 25,000ppm.” *Id.* (citing National Academy of Sciences Committee on Acute Exposure Guideline Levels). Dr. Osinubi cited the relationship between chemical exposure and respiratory disease, stating “[s]ince the respiratory tract has only a finite number of reactions (hyper reactive airways, airway/alveolar fibrosis and tissue destruction; cancer) to an infinite number of injurious exposure insults, by analogy, it is expected that intense irritant inhalation exposures to vinyl chloride

that cause a chemical pneumonitis, can result in one or more of these long term pulmonary conditions.” *Id.* at 20; *see also id.* at fns. 13-17 (citing peer reviewed literature to support these points).

In her addendum report of March 3, 2015, Dr. Osinubi reviewed additional medical record of Alice Breeman from both before and after the incident. Dr. Osinubi concluded that the during the period from 2008 through 2013 “even though she had a remote history of largely quiescent asthma, she did not present to her physician with asthma symptoms or lower respiratory tract problems, except for an episode relating to an oral chemical exposure in February 2012. Subsequent to the vinyl chloride derailment, Ms. Breeman presented with symptoms of hyper reactive airways/asthma, in addition to other acute symptoms that are known to be associated with high levels of vinyl chloride exposure. The medical records data demonstrate that Ms. Breeman has had an exacerbation of lower respiratory tract symptoms/reactive airway symptoms and pneumonia since her exposure to vinyl chloride, which she now has some activity limitations that adversely impacts on her quality of life. *See* Cuker Dec. Ex. J, Dr. Osinubi Addendum Report, p. 16. Dr. Osinubi ordered a pulmonary function test which revealed reduced FEF 25-75% (only 34% of predicted). Cuker Dec. Ex. M. Dr. Osinubi states this suggests small airway disease. Osinubi Dec. ¶ 34.

Dr. Osinubi wrote a second addendum report, on May 7, 2015, which

incorporates the pollutant dispersion model of Dr. Panos Georgopoulos. *See* Cuker Dec. at Ex. F (“May 2015 Osinubi Report”). Dr. Osinubi reported that Dr. Georgopoulos’s dispersion modeling showed vinyl chloride levels in the range of 4,000ppm in the area where Ms. Breeman was traveling between 7:00 a.m. and 8:00 a.m. and in excess of 1,500ppm between 8:00 and 9:00 a.m. The modeling also estimated vinyl chloride decay product concentrations from 100 to 1,000 mg/m³, which would more likely than not include 50% hydrochloric acid (HCL). This would substantially exceed the AEGL-2 level for disabling symptoms for hydrochloric acid and possibly exceed the AEGL-3 level. Dr. Osinubi noted that both hydrochloric acid and formaldehyde, the primary decay products of vinyl chloride, irritate the respiratory tract, cause coughing, shortness of breath, irritate the skin. *See* Cuker Dec. Ex. F, May 2015 Osinubi Report at 6-7. She concluded that “the acute symptoms experienced by Paulsboro residents, inclusive of Ms. Alice Breeman and Mr. Ronald Morris, in the aftermath of the massive vinyl chloride release is consistent with what is known as health effects of vinyl chloride and its decay products, inclusive of hydrochloric acid, formaldehyde and other(s).” *Id.* at 12.

ARGUMENT

“The Rules of Evidence embody a strong and undeniable preference for admitting any evidence which has the potential for assisting the trier of fact.”

Kannankeril v. Terminix Int'l Inc., 128 F.3d 802, 806 (3d Cir. 1997) (citing *Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777, 780 (3d Cir. 1996)); *see also* Fed. R. Evid. 402 (“Relevant evidence is admissible.”). If expert evidence is admissible, the trier of fact will determine the proper weight to give it. *Maloney v. Microsoft Corp.*, 2011 U.S. Dist. LEXIS 127870, at *6-7 (D.N.J. Nov. 4, 2011).

In considering pre-trial challenges to expert testimony, Rule 702 has “three major requirements: (1) the proffered witness must be an expert, *i.e.*, must be qualified; (2) the expert must testify about matters requiring scientific, technical or specialized knowledge; and (3) the expert’s testimony must assist the trier of fact.” *Pineda v. Ford Motor Co.*, 520 F.3d 237, 244 (3d Cir. 2008).⁵ “A district court’s inquiry under Rule 702 is ‘a flexible one’ and must be guided by the facts of the case.” *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 294 (3d Cir. 2012).

I. Dr. Osinubi did not rely on the NTSB’s report.

Defendants falsely claim that Dr. Osinubi “*relied* upon the NTSB Accident Report and Factual Report as the underlying basis for *all* of her opinions in this case.” Defs. Br. at 6 (emphasis added). Although Dr. Osinubi reviewed the NTSB’s Accident Report, she did not “rely” on it to support her substantive opinions. On the contrary, she relied on a mountain of other exposure-levels evidence (cited above), including the Air Quality Consultation of the New Jersey

⁵ Defendants do not challenge Dr. Osinubi’s qualifications.

Department of Health and the Air Modeling Report of Dr. Georgopoulos, both of which confirm that the levels were, in fact, very high. *See, e.g.*, December 2014 Osinubi Report at 18 (“Much of the area of Paulsboro is within 0.8 miles of the train derailment vinyl chloride release and based on air modeling data would have been exposed to 4,800 ppm or more of vinyl chloride on the day of the accident.”); *see* Cuker Dec. Ex. J, Dr. Osinubi Addendum Report at 15 (replicating NJ DOH data).

During her deposition, Dr. Osinubi referenced the NTSB, NJ DOH, the EPA, ALOHA modeling, and Dr. Georgopoulos collectively merely to note the universal agreement of credible sources that exposure levels were very high. *See* Cuker Dec. Ex. G, Dr. Osinubi Dep. at 91-92. Her casual reference to the NTSB is inconsequential to the opinions she will offer at trial. Defendants’ argument for exclusion under 49 U.S.C. § 1154(b) is thus a red herring and should be summarily rejected.

II. Dr. Osinubi used well-established and generally accepted methodology to opine on general causation.

Dr. Osinubi’s general causation methodology is not only logical but generally accepted in her field and the courts. She looked to see if there was a high exposure, and (since there was such an exposure) whether the symptoms experienced by the plaintiff began shortly after the exposure and were consistent with what would be expected to result from it. *See* Osinubi Dec. at ¶ 3. This was

the identical methodology used by the New Jersey Department of Health in its own health consultation for Paulsboro and accepted by Dr. Greenberg (Defendants' expert) himself. *See id.* at ¶ 5.

A. Dr. Osinubi's general causation opinion easily survives under *Kannankeril v. Terminix Int'l*, 128 F.3d 802 (3d Cir. 1997).

In *Kannankeril*, the plaintiff claimed she had a cognitive impairment caused by exposure to pesticides applied by Terminix. The trial court struck the expert's causation testimony on grounds that there was no air-testing sufficient to support the expert's opinion about the plaintiff's exposure and that the expert's opinion on causation was unreliable and unsupported by fact, the same arguments made by Defendants here. The Third Circuit reversed. In discussing the exposure, the Third Circuit rejected the notion that the plaintiff's expert had to rely on ambient air tests (which were not conducted until 9 months after the application of pesticides), and found it sufficient for the expert to look at Terminix's application records showing when, how much and where pesticide had been applied.

Kannankeril, 128 F.3d at 808-809. Critical to the instant motion, the Third Circuit in *Kannankeril* held that "*all factual evidence* of the presence of the chemicals in the residence should be relevant in forming an expert opinion of causation." *Id.* at 809 (emphasis added). The Third Circuit's holding cements the principle that *Daubert* reliability determinations must be made upon consideration of the full

evidentiary record, which will dictate whether or not certain exclusionary principles are apt.

In this case, although there are no precise measurements of Plaintiffs' exposure, it is undisputed that 23,000 gallons of vinyl chloride were released into the environment and that this amount of vinyl chloride would fill up a cloud over 27,000 cubic meters in size of 100% Vinyl Chloride. This is more than analogous to the "application records of how much pesticide was applied" in the *Kannankeril* case. If that were not enough, there is substantial evidence that Plaintiffs drove through the fog multiple times and in close proximity to the derailment site. And then there is Dr. Georgopoulos's model and the NJ DOH report, both of which document extensive levels of exposure and demonstrate that Plaintiffs' locations on November 30, 2012 subjected them to those high levels.⁶

In *Kannankeril*, the expert's methodology was indistinguishable from that employed by Dr. Osinubi here: "The temporal relationship and nature of her complaints led me to conclude that with reasonable medical certainty the cause of Dr. Kannankeril's central nervous system manifestations of toxicity is exposure to

⁶ Because this extensive exposure evidence supports Dr. Osinubi's opinions, there is no need to discuss Defendants' pointless attack on the ALOHA model. *See* Defs. Br. at 13-15. In addition, we respond to the attack on Dr. Georgopoulos's air model in our opposition to Defendants' motion (ECF No. 737) to exclude his testimony. It suffices to say here that "when direct measurements cannot be made, exposure can be measured by mathematical modeling, in which one uses a variety of physical factors to estimate the transport of the pollutant from the source to the receptor." Reference Manual on Scientific Evidence, p. 424 (2d ed. 2000).

Dursban.” *Kannankeril, supra*, 128 F.3d at 805. The Third Circuit concluded that because the plaintiff’s expert had based his opinion on the plaintiff’s medical records and reports of the volume of pesticide applied and his general experience, general medical knowledge, standard text books, and standard references, the experts “opinion on causation has a factual basis and supporting scientific theory.”

There is a legion of case-holdings in line with Dr. Osinubi’s methodology – that an acute exposure closely followed by symptoms known to result from that exposure provides good grounds for an expert’s opinion on causation. *See, e.g.*, *Thomas v. CMI Terex Corp.*, 2009 U.S. Dist. LEXIS 86623, at *40 (D.N.J. Sept. 21, 2009) (Simandle, J.) (“The question of causation can be resolved by a doctor without even medical testing, where the temporal proximity between an accident and the subsequent injury make the accident the most probable cause of the injury.”) (and collecting cases). In *Winnicki v. Bennigan’s, et al.*, 2006 U.S. Dist. LEXIS 5568 (D.N.J. Feb. 9, 2006) (Greenaway, Jr.), for example, the court evaluated expert testimony in a case in which the plaintiff ate a Caesar salad the night before she became sick with acute gastrointestinal dysfunction, which led to kidney failure and death. Although the expert could never determine exactly what was wrong with the salad, he opined that the salad was the cause of the condition using a differential diagnosis and temporal relationship. The court denied the defendant’s motion to exclude the expert, citing Third Circuit precedent (*e.g.*,

Kannankeril) accepting “medical testimony that relies heavily on a temporal relationship between and illness and a causal event.” *Id.* at *46.

B. Causation can be established in the absence of a precise measurement of Morris’s level of exposure, particularly where, as here, there is abundant evidence of substantial exposure.

The only distinction between the defense expert’s (Dr. Greenberg) methodology and that of Dr. Osinubi is that Dr. Greenberg would require idiosyncratic measurement of exposure to conclude that there is a completed exposure pathway. *Cf.* Osinubi Dec. at ¶¶ 4, 6. But that was not required by the New Jersey DOH, nor is it required by the pertinent case law.⁷ As the Third Circuit explained in *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 157 (3d Cir. 1999), “even absent hard evidence of the level of exposure to the chemical in question, a medical expert could offer an opinion that the chemical caused plaintiff’s illness.” As another court has explained, in rejecting a railroad’s *Daubert* challenge:

We disagree with CSX that in order to validate the testimony of the medical experts, Moody was required to prove the precise dosage of solvents to which he was exposed and the precise level required to have a harmful effect on human beings. * * * He presented testimony concerning how often he used the offending solvents and the duration of his exposure. He further explained the physical symptoms that he suffered while working with the solvents. While not quantitatively specific, the

⁷ Of course, record evidence already shows that, according to the New Jersey DOH, “[i]n Paulsboro there *was* a completed exposure pathway to Vinyl Chloride in the hours and days following the derailment” Osinubi Dec. at ¶ 7 (quoting NJ DOH Air Quality Health Consultation, p. 6) (emphasis modified).

expert testimony supports the conclusion that Moody's exposure, under the circumstances described, and his length of the exposure, are sufficient to cause his toxic encephalopathy.

CSX Transp., Inc. v. Moody, 2007 Ky. App. LEXIS 208, at *18-19 (Ky. Ct. App. July 13, 2007); *see also Whitlock v. Pepsi Ams.*, 527 Fed. App'x 660, 661-662 (9th Cir. 2013) ("Plaintiffs' **probable** ingestion of TCE-contaminated groundwater," coupled with the fact "that the alleged TCE and chromium exposure levels were 'within [a] reasonable range of that known [from several studies] to induce' the alleged injuries" was sufficient for expert testimony to satisfy *Daubert*; "Whether [that testimony] proves causation is not a question of admissibility.") (emphasis added); *Louderback v. Orkin Exterminating Company*, 26 F. Supp. 2d 1298, 1306-07 (D. Kan. Oct. 14, 1998) (as long as expert considered facts of plaintiff's exposure, the temporal relationship between exposure and disease, the plaintiff's medical records and history of disease, then an expert's opinion on causation is considered reliable and clearly "has a factual basis and supporting scientific theory" even when there is no specific evidence of exposures in excess of the ACGIH threshold level or the EPA reference dose); *Harris v. Peridot*, 313 N.J. Super 257, 298 (N.J. Super. Ct. - App. Div. 1998) (holding that an expert could reasonably consider the fact that the injuries sustained are consistent with a high level of exposure on "both sides of the equation", i.e. as additional evidence supporting the conclusion that the exposure was substantial).

C. The Bradford Hill factors are not a *per se* requirement, and do not apply in cases focusing on acute exposure.

While Defendants focus almost exclusively on the Bradford Hill methodology, it does not govern a case of acute exposure causing acute injury. *See* Osinubi Dec. at ¶ 1. As noted, *supra*, courts recognize that a strong temporal relationship and immediate symptomology can support a conclusion of causation. *See, e.g., In re Stand 'N Seal Prods. Liab. Litig.*, 623 F. Supp. 2d. 1355, 1371-72 (N.D. Ga 2009) (causation opinion that exposure caused chemical pneumonitis survived *Daubert* challenge because strong temporal relationship between exposure and acute onset of respiratory symptoms, despite lack of dose/response data); *In re Ephedra Prods. Liab. Litig.*, 2007 U.S. Dist. LEXIS 74914, at *7 (S.D.N.Y. Oct. 5, 2007), *vacated and remanded on other grounds by Giordano v. Market Am., Inc.*, 289 Fed. App'x 467, 469 (2d Cir. 2008) ("The close temporal proximity between Ms. Stafford's stroke and her use of ephedra, coupled with the general-causation evidence about ephedra's rapidly acting biological effects (in contrast to asbestos), permit a jury to infer that the dose she ingested was sufficient to be considered a substantial factor in causing her stroke."); *see also Cavallo v. Star Enter.*, 892 F. Supp. 756, 774 (E.D. Va. 1995) ("[T]here may be instances where the temporal connection between exposure to a given chemical and subsequent injury is so compelling as to dispense with the need for reliance on standard methods of toxicology."); *accord Nat'l Bank of Commerce v. Dow*

Chemical Co., 965 F. Supp. 1490, 1525 (E.D. Ark. 1996).

Sir Bradford Hill himself recognized that his viewpoints could be irrelevant in the case of acute exposure to indisputably toxic chemicals. *See* Osinubi Dec. at ¶ 1 (“A particular and perhaps extreme physical environment cannot fail to be harmful. A particular chemical is known to be toxic to man therefore suspect on the factory floor. Sometimes alternatively, we may be able to consider what might a particular environment do to a man ***and then see whether such consequences are, in deed, to be found.***”) (emphasis added); *see also Milward v. Acuity Specialty Prods. Group*, 639 F.3d 11, 17 (1st Cir. 2011) (“None of my nine viewpoints can bring indisputable evidence for or against the cause-and-effect hypothesis and none can be required as a sine qua non.”) (quoting Sir Austin Bradford Hill); Federal Judicial Center, Reference Manual on Scientific Evidence 600 (3d ed. 2011) (“There is no formula or algorithm that can be used to assess whether a causal inference is appropriate based on these guidelines. One or more factors may be absent even when a true causal relationship exists.”). Dr. Osinubi, for her part, acknowledged the Bradford Hill viewpoints and provided a sound basis for her alternate but consistent methodology.⁸

⁸ Defendants’ invocation of the latinism “*post hoc, ergo propter hoc*,” *see* Def. Br. at 10, is unavailing. Dr. Osinubi does not base her opinion that Plaintiffs’ exposure to vinyl chloride was substantial solely as a result of their symptomology; she bases it on evidence that Plaintiffs were situated in an area pummeled by mass quantities of vinyl chloride gas.

D. Vinyl chloride odor thresholds provide an acceptable basis for assessing exposure .

Defendants' argument that “[o]odor threshold is not a valid and reliable technique for determining” chemical exposure, Defs. Br. at 12 (citing only their own expert) is false.⁹ Courts routinely recognize that odor threshold is admissible as evidence of exposure when actual measurements are not available. *See, e.g.*, *Taylor v. Union Pacific Railroad Co.* 2010 U.S. District LEXIS 96802, at *12-12, 24-26 (S.D. Ill. Sept. 16, 2010) (holding that experts could conclude the exposure to sulfuric acid in excess of OSHA limits occurred because the odor threshold was at least the OSHA limit and multiple workers could smell the odor); *BP Amoco v. Flint Hills Res.*, 2009 U.S. Dist. LEXIS 131282, at *16 (N.D. Ill. June 3, 2009) (odor threshold testimony deemed non-speculative and admissible); *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 614 (D.N.J. 2002) (same); *Roney v. Gencorp*, 2009 US Dist. LEXIS 85816 (S.D.W.V.) (denying *Daubert* challenge of expert who relied on odor threshold to estimate vinyl chloride exposure); *Lewis v. Airco*, Dkt # A-3509-08T3, 2011 NJ Super. Unpub. LEXIS 1914, at *20 (N.J. Super. Ct. - App. Div. July 15, 2011) (recognizing odor threshold as relevant to estimate exposure to vinyl chloride).

⁹ It is also disingenuous insofar as at least one of the Defendants has taken the exact opposite position in prior litigation. *Cf. Sunnycalb v. Csx Transp., Inc.*, 926 F. Supp. 2d 988, 998 (S.D. Ohio 2013) (“CSX argues that Dr. Green should have been allowed to testify about the odor threshold of ‘chlorine gas’”).

While Dr. Osinubi acknowledged a potential deficiency in using odor threshold with respect to a single, unique ‘smeller,’ she *also* testified that “most people” would smell the chemical if the exposure were high enough. *See* Osinubi Dep. at 88-89. And the exposure levels here *were* high enough, because a sizable portion of the surveyed population reported smelling and tasting unusual odors on the day of the derailment. *See* Cedar Dec. Ex. X, NJ DOH Health Consultation, p. 8.

E. Dr. Osinubi’s review of the New Jersey DOH survey does not diminish the reliability of any of her opinions.

The DOH survey results are plainly admissible as public reports under Fed. R. Evid. 803(8), and any challenge to the methodology used by the NJ DOH goes only to the *weight* the survey evidence should be ascribed. *Cf. In re Nautilus Motor Tanker Co.*, 85 F.3d 105, 113 (3d Cir. 1996) (“[P]ublic reports are presumed admissible in the first instance and the party opposing their introduction bears the burden of coming forward with enough ‘negative factors’ to persuade a court that a report should not be admitted.”); *Ellis v. Int’l Playtex, Inc.*, 745 F.2d 292, 303 (4th Cir. 1984) (“Playtex’s concern about the methodology of the studies should have been addressed to the relative weight accorded the evidence and not its admissibility.”). Defendants speculate that the survey evidence was “biased,” but that is hardly a sound basis for excluding a public survey. *Cf. Ellis*, 745 F.2d at 303 (“[A]llegations of bias are purely speculative. All epidemiological studies that

might implicate a manufactured product are conducted with the possibility of litigation on the horizon.”).

Moreover, Defendants mischaracterize the evidence by saying the survey was “self administered” when, in fact, there were two surveys, and the door-to-door survey variety had results very similar to the mailed survey and was not self administered. Nor is the result from the survey “counterintuitive” because “in some instances reported symptoms increased as the distance from the derailment site increased.” As Dr. Osinubi explained in deposition, decay products are a potential cause of the symptoms complained of, but they may not form until the vinyl chloride traveled some distance from the immediate area. *See* Cuker Dec., Exhibit G (4/14/15 Osinubi Dep.), pp. 130-132. In any event, the overall pattern strongly shows symptoms were much more prevalent in people living within 3,500 feet of the derailment than those who live further than 3,500 feet and certainly further than 4,500 feet. *Id.*

F. The absence of studies or literature assessing identical high-level, non-occupational acute exposure to vinyl chloride monomer does not at all render Dr. Osinubi’s general causation opinion inadmissible.

There is no requirement “that a medical expert must always cite published studies on general causation in order to reliably conclude that a particular object caused a particular illness.” *Heller v. Shaw Indus.*, 167 F.3d 146, 155 (3d Cir. 1999); *accord Kudabeck v. Kroger Co.*, 338 F.3d 856, 862 (8th Cir. 2003). That

precedent—which by itself should permit the Court to skip Defendants’ argument at pages 17-18 of their brief—was applied in *Best v. Lowe's Home Ctrs., Inc.*, 563 F.3d 171 (6th Cir. 2009), where the Sixth Circuit reversed exclusion of plaintiff’s medical expert, Dr. Moreno. The court stated:

Based on his medical knowledge, Dr. Moreno compiled a list of possible causes for the injury Lowe's strongest argument is that no published material confirms that inhalation of the chemical in Aqua EZ can cause anosmia. But 'there is no requirement that a medical expert must always cite published studies on general causation in order to reliably conclude that a particular object caused a particular illness.' Dr. Moreno did not arbitrarily 'rule in' Aqua EZ as a potential cause, but instead concluded from the MSDS sheet and his own knowledge of medicine and chemistry that the chemical it contains can cause damage to the nasal and sinus mucosa upon inhalation.

Id. at 180-181 (internal citation omitted).

Evidence of a chemical’s properties and known effects can be reliably applied to novel settings in the absence of medical literature directly on point. *See* Osinubi Dec. at ¶ 42 (“Defendants criticize my citation to studies of World Trade Center victims, or occupational exposures because they are ‘dissimilar.’ But there is no large compendium of studies of effects of a 23,000 gallon release of vinyl chloride into a community of 6,000 people. Under these circumstances physicians look to analogous conditions.”).¹⁰ Notwithstanding this, Dr. Osniubi has supplied

¹⁰ Quantitative and qualitative concerns about medical literature go the weight, not admissibility, in any event. *Cf. McCullock v. H.B. Fuller Co.*, 61 F.3d 1038, 1042

a massive amount of medical literature to support her conclusions, which can be seen in her reports and Declaration.

III. Dr. Osinubi reliably demonstrated that vinyl chloride exposure can be linked to respiratory disease among others.

A. Causation of Respiratory Disease

It is undisputed that vinyl chloride is a respiratory irritant, and that its decay products, HCL and formaldehyde, are even more irritating. *See, e.g.*, Osinubi Dec. at ¶¶ 20-22. And there is no question that exposure to a high level of Vinyl Chloride or its decay products, hydrochloric acid and formaldehyde, can cause respiratory problems. *See Id.*

The New Jersey Department of Health Hazardous Substance Fact Sheet for Vinyl Chloride states “Inhaling Vinyl Chloride can irritate the nose, throat and lungs,” *see id.* at ¶ 12, and Dr. Greenberg agrees that Vinyl Chloride is a respiratory irritant. *See id.* (citing Greenberg Dep. at 26:14-16).

Dr. Osinubi cites a wealth of peer-reviewed literature to support her opinion that exposure to respiratory irritants such as vinyl chloride “can result in long term respiratory sequelae, such as asthma, reactive airway dysfunction syndrome (“RADS”), bronchiolitis obliterans or constrictive bronchiolitis and vocal cord dysfunction. RADS is associated with a vapor, mist, fume or gas exposure that is

(2d Cir. 1995) (holding that peer review and publication or general acceptance of an expert's theory goes to the weight of the testimony rather than its admissibility).

extremely high level and brief, and causes people to develop permanent respiratory problems. *See* Osinubi Dec. at ¶ 15 (citing Greenberg Dep. at 197:13-19); (“Constrictive Bronchiolitis may occur where there is inhalation of gases, toxic fumes, or irritants such as Nitrogen Dioxide, Chlorine Gas, and Mustard Gas.”) (quoting *Small Airway Disease Related to Occupational Exposures* Gulatim, et al. Clin. Pulm. Med. Vol. 22, No.3, May 2013, Pg. 133,136).

A respected textbook in occupational medicine recognizes that “inhalational injury from high intensity exposures” such as those that occur in “transportation accidents” can have serious respiratory effects including irritation, inflammation, pneumonitis, asthma, pulmonary fibrosis and bronchiolitis obliterans.” *Id.* at 18-19. The same textbook confirms that “irritant induced asthma occurs … after substantial exposure to an irritating dust, mist, vapor or fume.” *Id.* at 20. A more recent article ascribes the emerging spectrum bronchiolar disorders from occupational and environmental exposures to a wide range of respiratory irritants. *See* Osinubi Dec. ¶ 30.

Hydrochloric Acid and Formaldehyde are both strongly irritating to the respiratory tract and associated with a wide range of adverse respiratory effects:

Vinyl Chloride Decay Toxicants	Health Effects
Hydrochloric acid ¹¹	<ul style="list-style-type: none"> Severe irritation of respiratory tract, characterized by

¹¹ Source: Hydrochloric Acid Material Safety Data Sheet.
<http://www.sciencelab.com/msds.php?msdsId=9924285>

Vinyl Chloride Decay Toxicants	Health Effects
	<p>coughing, choking, or shortness of breath. Severe over-exposure can result in death.</p> <ul style="list-style-type: none"> • Inflammation of the eye is characterized by redness, watering, and itching. • Skin inflammation is characterized by itching, scaling, reddening, or, occasionally blistering. • Repeated or prolonged exposure to spray mist may produce respiratory tract irritation leading to frequent attacks of bronchial infection.
Formaldehyde ¹²	<ul style="list-style-type: none"> • Corrosive: It causes skin irritation which may range from mild to severe with possible burns, brownish discoloration of the skin, urticaria, pustulovesicular eruptions, irritant and/or allergic dermatitis (eczema). • May be absorbed through the skin with symptoms paralleling those of ingestion. • Causes irritation of the respiratory tract (nose, throat, airways). Symptoms may include dry and sore mouth and throat, thirst, and sleep disturbances, difficulty breathing, shortness of breath, coughing, sneezing, wheezing rhinitis, chest tightness, pulmonary edema, bronchitis.... • Increased risk of asthma and/or allergy observed in humans breathing 0.1 to 0.5 ppm • Eczema and changes in lung function observed at 0.6 to 1.9 ppm • Central nervous system (CNS) effects include: excitement, CNS depression, somnolence, convulsions, stupor, aggression, headache, weakness, dizziness, drowsiness, and/or coma. • Causes gastrointestinal irritation with nausea, vomiting (possibly with blood), diarrhea, severe pain in mouth, throat and stomach. • Damages the kidneys, liver, central nervous system

¹² Source: Formaldehyde Acid Material Safety Data Sheet.
<http://www.sciencelab.com/msds.php?msdsId=9924095>

Vinyl Chloride Decay Toxicants	Health Effects
	<ul style="list-style-type: none"> Classified as carcinogenic by IARC, ACGIG, NTP.

Injuries caused by vinyl chloride and its decay products are analogous to injuries caused by relatively low-dose exposures to chlorine, *e.g.* in a swimming pool which generates hydrochloric acid. *See* Osinubi Dec. at ¶ 17 (citing *Short term respiratory effects of acute exposure to chlorine due to a swimming pool accident* OEM 2001; 58 399-404) (recent reports have documented long term effects, such as asthmatic reactions, bronchial hyper responsiveness, and reduced lung function among exposed people both in general and in the work environment). Dr. Osinubi has good grounds to analogize vinyl chloride to other solvents and respiratory irritants. Members of the medical science community have rightly observed that “[s]ometimes chemicals of a common type cause a generalized adverse response. For example, nearly all organic solvents from petroleum products . . . share some (but not all) symptoms in common: ‘defatting’ of the skin following dermal exposure, and central nervous system depression . . . following relatively high levels of inhalation exposure.” *In re Stand 'n Seal, supra*, 623 F. Supp. 2d at 1375 (quoting David L. Eaton, *Scientific Judgment and Toxic Torts - A Primer in Toxicology for Judges and Lawyers*, 12 J.L. & Pol'y 5, 10 (2003)).

Dr. Osinubi applied this wealth of scientific literature to the following fact

pattern of Ms. Breeman:

In the case of Ms. Breeman, she also experienced immediate irritant respiratory symptoms upon exposure to VC cloud for which she also sought emergency room treatment on two occasions. . . .

Although Ms. Breeman is yet to have a HRCT which is clearly medically indicated based upon the recommendations by the NIOSH article cited above, her reduced FEF 25-75% (only 34% of predicted) suggests small airway disease.

Ms. Breeman's exposure history to the vinyl chloride vapor cloud and its constituent highly irritative decay products of hydrochloric acid and formaldehyde, her clinical presentation, and her recent lung function tests are consistent with what has been described in small airways/bronchiolar disease following exposures to irritant chemicals (inclusive of hydrochloric acid) - as per the recent article by NIOSH.

Osinubi Dec. at ¶¶ 33-35 (citations omitted).¹³

B. Increased Risk of Cancer Justifying Medical Monitoring

Dr. Osinubi's opinion that the massive short-term exposure to vinyl chloride justifies medical monitoring because of increased cancer risk is supported by a substantial body of scientific evidence:

1. OSHA requires medical monitoring for workers exposed to vinyl chloride and specifically requires any employee who is exposed to a "massive release of vinyl chloride" as a result of a catastrophic mishap "shall be afforded appropriate medical surveillance." 29 CFR §1910.1017(b)(5) and §1910.1017(k)(3).
2. The National Academy of Sciences has calculated a 1 in 10,000 cancer risk associated with the following short term exposures to vinyl chloride:

¹³ Although Defendants also attack Dr. Osinubi's opinion regarding general causation of "chronic liver disease" she did not diagnose that condition in Ms. Breeman, so we will not address that here.

1 in 10,000 for a 30 minute exposure of 2,990 ppm or a one hour exposure of 670 ppm; or 1 in 10,000 for a 30 minute exposure of 1,180 ppm or a one hour exposure of 350 ppm. Osinubi Dec. ¶47.

3. In a study of cancer induction following single and multiple exposures to vinyl chloride, a single exposure to a high dose was found to cause cancer in mice, leading the author to conclude “one dose is sufficient if the dose is high enough.” *Cancer Induction Following Single and Multiple Exposures to a Constant Amount of Vinyl Chloride Monomer*, R. M. Hehir, Environmental Health Perspectives Vol. 41pgs. 63-72, 1981¹⁴.
4. Using an EPA algorithm for assessing excess cancer risk, Dr. Greenberg admitted that a 60 minute exposure at 4,800 ppm would result in an excess cancer risk of 1 in 11,170. At 90 minutes the incidence would be 50% higher or about 1 in 7,000.¹⁵

Even more concerning is the recent study of chromosomal aberration in persons exposed to a vinyl chloride train wreck in Germany. Cf. Osinubi Dec. ¶
48. In that case, the atmospheric concentration of vinyl chloride was not measured

¹⁴ Dr. Osinubi’s opinion cannot be excluded simply because she relied on animal studies. Cf. *In re Paoli R.R. Yard Pcb Litig.*, 35 F.3d 717, 743 (3d Cir. 1994)

¹⁵ Dr. Greenberg’s initial calculation using the EPA algorithm was one excess cancer in 333 Million, but he later admitted that this was mistaken by a factor of 1,000 and the actual increased cancer risk is one in 333,000. He based this upon an average exposure of 372 ppb, or 0.968 mg/m³ over an 18 day period. See Cuker Dec. at Exhibit H (Greenberg 6/16/15 Dep.), p.p. 105:5-109:7. Because Dr. Greenberg’s cancer risk assessment did not include any readings taken before the afternoon of November 30, see id. at 114:11-22, he was asked to assume that in lieu of the exposures he calculated over the 18 days, there was a single exposure of 4,800 ppm for an hour and asked to calculate an increased cancer risk on that. Using the same EPA algorithm, he concluded the increased cancer risk would be 29.81 times greater than the 1 in 333,000 cancer risk he had calculated earlier, which results in an excess cancer risk of 1 in 11,170. Id. at 114:23-122:25. Dr. Greenberg then admitted that if the exposure assumed was 4,800 ppm for 90 minutes, the cancer risk would go up by 50%, which would in turn result in an excess cancer risk of about 1/7,062, well in excess of the 1/10,000 standard universally regarded as an excess risk of concern. Id. at 123:13-18.

until 15 hours after the event, at which time it was 1 – 8 ppm, certainly no higher than what was found in Paulsboro. That study, which controlled for demographic variables and smoking showed those exposed to vinyl chloride had a statistically significantly increase in the mean frequency of aberrant cells. Dr. Osinubi has cited other articles showing “that a single exposure is effective as multiple exposures in producing chromosome damage” and that there is a significant correlation between chromosomal aberrations and the incidence of cancer. *See* May 2015 Osinubi Report at 14. Dr. Osinubi notes that mutant biomarkers have been found even in workers exposed below OSHA’s permissible exposure limit of 1 ppm. *Id.* at 14-15. Accordingly, there is a strong scientific basis to show that increased chromosomal aberrations would be expected to increase cancer risk. *See* Osinubi Dep. at 122:6-10 (“Chromosomal aberrations have been demonstrated to be predictive of cancer development in workers who have been exposed to vinyl chloride.”). Therefore, for all of these reasons Dr. Osinubi’s opinions on disease causation are amply supported in record and should not be excluded.¹⁶

C. Medical Tests to Evaluate GERD are Recoverable

Contrary to what Defendants claim, Dr. Osinubi does not opine that vinyl chloride exposure “caused” gastroesophageal reflux disease (GERD) in Ms.

¹⁶ Defendants’ attack on Dr. Osinubi’s opinions regarding sleep disorder has no place in this case, as Dr. Osinubi did not include these conditions within the differential diagnosis of Mr. Morris.

Breeman, but simply that exposure to respiratory irritants, such as vinyl chloride, formaldehyde and HCL can cause or aggravate irritant induced aerodigestive dysfunction syndrome. Osinubi Dec. at ¶41. Indeed, an increased incidence of these disorders have been found among persons exposed to the New York disaster area in the aftermath of the World Trade Center attacks and GERD has been specifically named as a disease for which compensation may be obtained for WTC exposures. 42 USC 300mm-22(a)(3)(A)(xi). Vinyl chloride, hydrochloric acid, and formaldehyde were all found in the complex mix of WTC exposures. Osinubi Dec. at ¶¶ 43, 45. Here, Dr. Osinubi simply recommends further evaluation and testing in light of Ms. Breeman's pre-existing GERD and the stressors associated with her exposures to vinyl chloride, and the inhalation irritant exposure from vinyl chloride which more likely than not exacerbates her GERD. *See id.* at ¶ 41.

Ms. Breeman is entitled to recover not only for injury already inflicted, but also for expenses reasonably necessary to avert further harm. *See Restatement 2d of Torts* § 919(2) ("One who has already suffered injury by the tort of another is entitled to recover for expenditures reasonably made or harm suffered in a reasonable effort to avert further harm.").¹⁷ Even if the testing were to show that

¹⁷ The first illustration to Section 919(2) is directly applicable here. "A negligently hits and bruises B's leg. B applies a dressing to the wound but, reasonably believing that the bone in his leg may be fractured, has X-ray photographs taken. These reveal no fracture. B is entitled to recover the expense of the X-ray photographs." *Restatement 2d of Torts* § 919(b), cmt. b, illustration 1.

Ms. Breeman's GERD had not been exacerbated by exposure to vinyl chloride, still the testing in order to avert further harm will have been reasonable. Thus, she is entitled to recover for it as an element of damages, and Dr. Osinubi's opinion concerning the need to test is properly admissible. *See Grassi v. Pennsylvania R. Co.*, 86 N.J. Super. 48, 55, 205 A.2d 895, 899 (App. Div. 1964) (It was not error to permit plaintiff's medical witness to testify that plaintiff's weekly treatment should continue, to guard against further injury occurring); *see also Theobald v. Angelos*, 40 N.J. 295, 304, 191 A.2d 465, 470 (1963) ("reasonable compensation" includes all expenses reasonably necessary or incidental to plaintiff's efforts to cure or alleviate his injuries).

IV. Dr. Osinubi Properly Accounted for Alternate Causes

The reliability of differential diagnosis has been approved in this circuit. *Heller, supra*, 167 F.3d at 154-155 (3rd Cir 1999); *Paoli III*, 35 F.3d 717, 742, n.8 (3rd Cir. 1994). "To properly perform a differential diagnosis, an expert must perform two steps: (1) 'Rule in' all possible causes of [injury] and (2) 'Rule out' causes through a process of elimination whereby the last remaining potential cause is deemed the most likely cause of [injury].'" *Feit v. Great W. Life & Annuity Ins. Co.*, 271 Fed. App'x 246, 254 (3d Cir. 2008). Furthermore, expert testimony on causation is not inadmissible "simply because it fails to account for some particular condition or fact which the adversary considers relevant." *Creanga v. Jardal*, 185

N.J. 345, 360 (2005).

Defendants claim that “Dr. Osinubi fails to address plausible alternative causes in her report.” Def. Br. at 24. Shortly thereafter, however, Defendants concede that Dr. Osinubi “acknowledges that Plaintiff had a pre-existing history of asthma and is a current smoker” and that she rejects those as exclusive causes of her symptomology. *Id.* So Defendants move on to briefly critique the *method* by which Dr. Osinubi excludes potential other causes as nothing more than “her own say-so.” *Id.* at 25. But Defendants then recognize that Dr. Osinubi in fact rejected “alternative causes . . . based primarily on temporality.” *Id.* Defendants’ challenge to Dr. Osinubi’s differential diagnosis thus goes nowhere. *See also Heller, supra*, 167 F.3d at 154 (“Both a differential diagnosis and a temporal analysis, properly performed, would generally meet the requirements of *Daubert* and *Paoli*.”).

And that is exactly what Dr. Osinubi did here. She found that, notwithstanding her smoking history. Ms. Breeman’s largely quiescent asthma, and lack of lower respiratory complaints except for a chemical spill in February 2012, contrasted sharply with the symptoms of hyper reactive airways/asthma that followed the derailment, showing the irritant chemical exposure to be the exacerbating cause. Cuker Cert. Ex. J, p. 16.

IV. Defendants remaining arguments can be dismissed out of hand.

Morris was indisputably exposed to high levels of a known human

carcinogen as a result of the derailment, he required immediate medical attention, and deleterious health effects persist to this day. Because, as set forth, *supra*, Dr. Osinubi's opinions on long-term risks associated with acute vinyl chloride exposure are well supported in the medical literature, her opinions—far from speculative, *cf.* Defs. Br. at 25—are admissible and can be used as the basis for Morris's medical monitoring claim. *Cf. Theer v. Philip Carey Co.*, 133 N.J. 610, 627 (N.J. 1993) (“[P]laintiffs who have suffered increased risk of cancer when directly exposed to a defective or hazardous product like asbestos, when they have already suffered a manifest injury or condition caused by that exposure, and whose risk of cancer is attributable to the exposure.”).¹⁸

Finally, in support of Defendants' contention that Dr. Osinubi's testimony should be excluded under Fed. R. Evid. 403 they merely parrot the rule and state: “the probative value of Dr. Osinubi's opinions is clearly outweighed by [the Rule 403] concerns.” Defs. Br. at 27. The argument is thus undeserving of review by this Court. *Cf. Nagle v. Alspach*, 8 F.3d 141, 143 (3d Cir. 1993) (declining appellate review of issue mentioned just “casually in one sentence.”).

CONCLUSION

For all of the reasons given above, Defendants' motion to exclude the testimony of Dr. Osinubi in this case should be denied.

¹⁸ The appropriateness of medical monitoring relief under New Jersey law is the subject of separate motions by Defendants.

DATED: June 19, 2015

Respectfully submitted:

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CERTIFICATE OF SERVICE

I certify that on today's date a true and correct copy of Plaintiffs' brief in opposition to Defendants' motion to exclude the testimony of Dr. Osinubi was electronically filed with the Court's CM/ECF system, which will accomplish service of same on all counsel of record.

Dated: June 19, 2015

/s/ *Mark R. Cuker*
Mark R. Cuker, Esq.